# Public Comments on Peer Review of the BG1Luc ER TA Assay

SACATM

June 16 – 17, 2011

Catherine Willett, PhD
Associate Director
Regulatory Testing
People for the Ethical Treatment of Animals

## Supported recommendations

Main finding: the Lumi-Cell (BG1Luc) ER TA test method is a scientifically valid method for assessing the *in vitro* estrogen agonist and antagonist activity of compounds within a test battery or tiered testing scheme

# Supported recommendations

Other recommendations:

- the BG1Luc ER TA test be considered as an alternative for
  - (CERI STTA) and the
  - rat uterine cytosol (RUC) ER binding assay
    - (positives be confirmed using a pure ER antagonist)
- recombinant ER binding assays to replace the RUC ER assay
- development and use of a metabolism component is critical
- data evaluation should include potency evaluations
  - quantification of activity
  - relative to known reference substances
  - including associated uncertainty
- evaluate the quality of the data used to classify ICCVAM reference substances
- discuss the use of the assay within the context of EPA's Endocrine Disruptor Testing Program (EDSP)
- Consider other potential uses that would reduce animal use

# Additional recommendations

Evaluate and update chemical reference list:

- Panel recommendation to evaluate the quality of data used to characterize reference chemicals
- Follow-up by:
  - revising chemical list
  - adding new information to searchable public database (e.g. ToxRefDB)

Ensure that the best characterized chemicals are used for future assay evaluations

Identify new reference chemicals in underrepresented chemical classes

# Additional recommendations

Considerations of use to reduce animal testing:

- In addition to screening and prioritization
- Revising structure of EDSP Tier 1
  - *In vitro* assessment prior to animal testing
- Weight-of-evidence (WoE) approach
  - reduce or eliminate ER-related animal tests
    - uterotrophic
    - rat pubertal
    - fish short-term reproduction

# Additional recommendations

Quantitative Comparison to CERI STTA:

- Panel recommendation to evaluate data quantitatively
  - relative to reference chemical
  - Relative Potency Index (in addition to EC50)
- Allows direct comparison between assays that may use different assessment methods and decision criteria
  - e.g. CERI STTA assay
  - Uterotrophic - ?

# Additional recommendations

Length of Time to Complete Study :

- Review took seven years
- BG1Luc ER TA not included initial phase(s) of the EDSP
- More efficient process needed in light of large number of new assays

Panel report should include:

- issues that contributed to the length of the review
- recommendations for avoiding these issues in future reviews

Thank you